Chirotronics
Model D – 510(k) Notification Submission

20 September 2007

K073132

APR - 3 2008

510(k) Summary of Safety and Effectiveness

Device Description

Device Trade Name:	Model D
	Disc Force
Common Name:	Traction Equipment
Classification Name:	Powered Traction Equipment
Class:	Class II
Reference:	21 CFR 890.5900
Product Code:	ITH
Panel Code:	890 – Physical Medicine

Predicate Devices:

K981822 – DRS
K023160 – DRX500
K060735 – DRX9000

Intended Use:

The Model D provides a program of treatments for the relief from pain for those patients suffering from low back pain and neck pain. Each treatment consists of a physician prescribed treatment period on the Model D and is designed to provide static, intermittent, and cycling distraction forces to relieve pressure on structures that may be causing low back and neck pain. It achieves this through decompression of intervertebral discs – unloading due to distraction and positioning. Conditions which may be treated by this methodology include back and neck pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica.

Technological Characteristics:

The Model D incorporates various principles and working characteristics of the predicate devices. The incorporation of a traction device with a flat surface type powered bed remains the same, and the new overall appearance of the apparatus has not impacted on or changed the safety and effectiveness of the device.

Device Description:

The main parts of the Model D are as follow:

1. The bed is a stand on / stand off type of bed that can be tilted to allow the fully clothed patient to step onto a footrest while in the vertical position and then be slowly lowered to the horizontal treatment position using a remote control hand held by the practitioner.
2. The bed is split into two cushions which slide on low friction runners only in the horizontal plane and which can be locked independently.

3. Distraction tensions are applied to the patient via a pelvic harness while the upper torso is anchored to the locked cephalic cushion via a chest harness. The lower cushion, on which the lower torso of the patient rests, is unlocked and able to slide freely, thus negating any frictional movement between the patient and the bed cushions during the application of distraction forces and ensuring the efficiency of the application of the prescribed force.
4. The distraction unit is mounted to a vertical movable platform incorporated into a support tower at the foot end of the bed. This enables the distraction tensions to be applied at differing angles (ranging from 0 to 27 degrees) to the patient.
5. The distraction unit is programmable and controlled from a control panel fitted into the tower to provide static or intermittent distraction.
6. The minimum and maximum distraction settings are 0 - 200 pounds.
7. Treatment parameters, such as time and tension, are continuously monitored and displayed by the control panel during set up and during treatment.
8. At the conclusion of the duration of the treatment session, the tension always returns to zero.
9. A flat panel monitor, which is incorporated in a separate section of the control tower, with headphones provides comfort and relaxation to the patient and / or educational opportunities.
10. The system incorporates a Patient Interrupt Switch; an Emergency Interrupt Switch; and a Power Switch, which, when selected independently, in tandem, or in unison, results in the immediate release of all tension.
11. The Model D will not operate if the Patient Switch is not working properly or has not been tested prior to the commencement of each treatment session.
12. If the Patient Interrupt Switch, or the Emergency Interrupt Switch is activated during a session, or power is interrupted, all treatment parameters must be manually re-entered before the treatment session will restart.

Summary of Safety and Effectiveness:

The Model D has been designed to be safe and effective. The primary characteristics for safety and effectiveness include:

1. The bed actuator activation is via a 24-volt electric circuit.
2. The control unit of the distraction unit, including the Patient Emergency Switch's power supply is a maximum of 24 volts.
3. The patient steps onto the bed while it is in the vertical position and is then reclined into the treatment position under the supervision of the attendant, and does not have to climb onto the treatment bed.
4. Adjustable handgrips are fitted for patient support during the reclining of the bed.
5. There is an audible warning signal when the unit is first turned on, when the treatment session is complete, when the Patient Interrupt Switch is tested or activated during a treatment session.

6. Anytime a session is interrupted, whether as a result of patient input via the Patient Interrupt Switch; attendant input via the Stop Session switch, or Power Switch; or power interruption, there is an instantaneous release of all tensions. In any of these instances, the treatment program has to be manually reentered into the control panel before treatment can re-commence.
7. All treatment parameters must be physically inputted each time a session occurs.
8. There is limited vertical movement of the traction head.
9. There is a permanent visible means of indication of the angle of distraction pull.
10. The system defaults to a maximum tension of 200 pounds for lumbar session and 30 pounds for a cervical session if an amount greater than these are inadvertently entered by the physician.
11. If a tension amount greater than one-half of the patient's body weight is entered, a warning box must be responded to before the session can start.

Similar types of devices have been successfully manufactured and marketed in this country for over ten years with no evidence of MDR events.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

North American Medical Corp (NAM)
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, MN 55313

APR - 3 2008

Re: K073132
Trade/Device Name: Model D Disc Force
Regulation Number: 21 CFR 890.5900
Regulation Names: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: March 18, 2008
Received: March 19, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): *not known*

Device Name: *Model D- "Disc Force"*

Indications for Use:

The *Model D – Disc Force* provides a program of traction type treatments for relief from pain for patients suffering with low back pain and neck pain. Each treatment consists of a physician prescribed treatment period on the *Model D - Disc Force* and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back or neck pain. Conditions that may be treated include neck and back pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of inter-vertebral discs, that is, unloading due to distraction and positioning.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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